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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,659	02/25/2002	Maurice Cohen	6171.US.D2	6272

23492 7590 10/12/2004

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 10/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/082,659	COHEN ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 6, 2004 has been entered.

2. Claims 1-9 are pending.

Claims 5-9, drawn to non-elected inventions are withdrawn from examination.

Claim 1 has been amended.

Claims 1-4 are examined on the merits.

Withdrawn Rejections

Claim Rejections - 35 USC § 101

3. The rejection of claims 1-4 under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, credible or asserted utility or a well established utility is withdrawn.

Claim Objections

4. Claim 1 is objected to because of the following informality: because it does not read properly. Applicants are advised to include the preposition "of" between words, consists and a.

Maintained Rejection

Claim Rejections - 35 USC § 112

5. The rejection of claims 1-4 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained.

Applicants have amended claim 1 expecting to obviate the instant rejection, see Remarks submitted August 6, 2004, page 4, second paragraph. Applicants state that "[t]he claims now require that the polynucleotide consists of a specific and definitive sequence and its complements." The Examiner has considered the amendment and the arguments and has found these assertions unpersuasive.

Claim 1 has been amended to "...said polynucleotide consists a sequence selected from the group consisting of SEQ ID NO: 4 and complements thereof." While it is clear that the polynucleotide claimed *must consists* of SEQ ID NO: 4, 312 nucleic acid residues, the complements thereof are not clearly defined. Accordingly, it still stands to reason that the complements of SEQ ID NO: 4 are undefined. This phrase reads on any size molecule with any level of sequence complementarity. Applicants have not presented data that supports the use of

arbitrary sized complements effectiveness in methods of detecting a target polynucleotide or mRNA within a test sample (such as blood, urine, saliva and stool) in order to assess whether or not the test sample contains a polynucleotide indicative of prostate cancer, see page 57, lines 9-13; page 59, lines 30-34; and page 80, lines 1-10. These diagnostic methods include for example hybridization techniques, polymerase chain reaction, as well as reverse transcription polymerase chain reaction.

Applicants' specification has not evidenced enabling disclosure in which a definitive prostate cancer diagnosis can be made with any complement of SEQ ID NO: 4. It is questionable that one of ordinary skill in the art would be able to arbitrarily select a complement of SEQ ID NO: 4 and implement this sequence in a method of diagnosis. The specification continues to be remiss of support enabling the skilled artisan to implement undefined complements of SEQ ID NO: 4 in any form of cancer diagnosis. The specification does not enable one of ordinary skill in the art to definitively assess the incidence of any type of cancer, particularly prostate cancer in a test sample with a complement of SEQ ID NO: 4. There is no disclosure designating which complements or what criteria is used for discerning which nucleic acid residues would be effective in any diagnostic method. The experimental design presented in the specification lacks information regarding the applicability of complements of SEQ ID NO: 4 in diagnostic methods relative to prostate diseases.

Based on the analysis set forth it would require undue experimentation for the skilled artisan to practice this invention because there is no support in the

specification for the enablement of the broadly claimed invention. Therefore, in view of the insufficient guidance in the specification, extensive experimentation would be required to enable the claims.

New Grounds of Rejection

Claim Rejections - 35 U.S.C. § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent number 6,620,922 (filing date February 25, 1997). Applicants' claim language reads "...polynucleotide consists [of] a sequence selected from...SEQ ID NO: 4 and complements thereof". In particularity the "complements thereof" phrase embraces a genus of polynucleotides of any size and any amount of sequence complementarity. Accordingly, the following rejection is set forth. Sequence 435 of U.S. patent #6,620,922 discloses a complement of SEQ ID NO: 4, see attached database sheet. The polynucleotide is produced by *in vitro* recombinant DNA techniques, as well as by synthetic techniques, see column 26, lines 4-8; column 27, lines 39-49; columns 29, line 47-column 35, line 2. The disclosed polynucleotide comprises a sequence, which encodes at least one epitope, column 53, lines 1-13.

8. Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent number 6,395,278 (filing date February 25, 1997). Applicants' claim language reads "...polynucleotide consists [of] a sequence selected from...SEQ ID NO: 4 and complements thereof". In particularity the "complements thereof" phrase embraces a genus of polynucleotides of any size and any amount of sequence complementarity. Accordingly, the following rejection is set forth. Sequence 435 of U.S. patent #6,395,278 discloses a complement of SEQ ID NO: 4, see attached database sheet. The polynucleotide is produced by *in vitro* recombinant DNA techniques, as well as by synthetic techniques, see bridging paragraph of columns 18 and 19; column 22, lines 51-53. The disclosed

polynucleotide comprises a sequence, which encodes at least one epitope, column 25, lines 42-47.

9. Claims 1-3 is rejected under 35 U.S.C. 102(b) as being anticipated by Boehringer Mannheim Biochemicals 1991 Catalog, page 557. Applicants' claim language reads "...polynucleotide consists [of] a sequence selected from...SEQ ID NO: 4 and complements thereof". In particularity the "complements thereof" phrase embraces a genus of polynucleotides of any size and any amount of sequence complementarity. Accordingly, the following rejection is set forth. Boehringer's catalog discloses a chemically synthesized mixture of hexanucleotides containing all possible 6-nucleotide sequences.

RESULT 10
US-09-352-616A-435/c
; Sequence 435, Application US/09352616A
; Patent No. 6395278
; GENERAL INFORMATION:
; APPLICANT: Dillon, Davin C.
; APPLICANT: Harlocker, Susan Louise
; APPLICANT: Jiang, Yuqui
; APPLICANT: Xu, Jiangchun
; APPLICANT: Mitcham, Jennifer Lynn
; TITLE OF INVENTION: COMPOUNDS FOR IMMUNOTHERAPY AND DIAGNOSIS
; TITLE OF INVENTION: OF PROSTATE CANCER AND METHODS FOR THEIR USE
; FILE REFERENCE: 210121.427C8
; CURRENT APPLICATION NUMBER: US/09/352,616A
; CURRENT FILING DATE: 1999-07-13
; NUMBER OF SEQ ID NOS: 472
; SOFTWARE: FastSEQ for Windows Version 3.0
; SEQ ID NO 435
; LENGTH: 424
; TYPE: DNA
; ORGANISM: Homo sapiens
US-09-352-616A-435

Query Match 97.4%; Score 304; DB 4; Length 424;
Best Local Similarity 100.0%; Pred. No. 2.9e-92;
Matches 304; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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Qy          9 GTTTGCTCTGAATTTATTGCGAGTGAAAAACAGAGAAAATCCTCAAGTTTAAGTTTCTGA 68
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        424 GTTTGCTCTGAATTTATTGCGAGTGAAAAACAGAGAAAATCCTCAAGTTTAAGTTTCTGA 365

Qy         69 TAGCAGAGTGTGGGAGTTAGAGCATGGGGAGTCCAGAGGTTCCAGACCCCCAAAGGTCTC 128
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        364 TAGCAGAGTGTGGGAGTTAGAGCATGGGGAGTCCAGAGGTTCCAGACCCCCAAAGGTCTC 305

Qy        129 TACCAGGGCCATCTCCGTTAGTGGCGGTGGCAGCCCCTCTTGTGGCCTTTTTCCTCTCTC 188
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        304 TACCAGGGCCATCTCCGTTAGTGGCGGTGGCAGCCCCTCTTGTGGCCTTTTTCCTCTCTC 245

Qy        189 CAAGGGGTCACCCCGCACCATGCCGCTCCCCCTCATCTATCTTGCCCCCTCCCCACAGGC 248
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        244 CAAGGGGTCACCCCGCACCATGCCGCTCCCCCTCATCTATCTTGCCCCCTCCCCACAGGC 185

Qy        249 CCATCTGCGCTGAACTCTCGCCAGTTCCGAAGTCGGCGAGGGAGGGGGTTTACTTGCCCG 308
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        184 CCATCTGCGCTGAACTCTCGCCAGTTCCGAAGTCGGCGAGGGAGGGGGTTTACTTGCCCG 125

Qy        309 ATCG 312
              ||||
Db        124 ATCG 121
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RESULT 11
US-09-636-215-435/c
; Sequence 435, Application US/09636215
; Patent No. 6620922
; GENERAL INFORMATION:
; APPLICANT: Xu, Jiangchun
; APPLICANT: Dillon, Davin C.
; APPLICANT: Mitcham, Jennifer L.
; APPLICANT: Harlocker, Susan L.
; APPLICANT: Jiang, Yuqui
; APPLICANT: Henderson, Robert A.
; APPLICANT: Kalos, Michael D.
; APPLICANT: Fanger, Gary R.
; APPLICANT: Retter, Marc W.
; APPLICANT: Stolk, John A.
; APPLICANT: Day, Craig H.
; APPLICANT: Vedvick, Thomas S.
; APPLICANT: Carter, Darrick
; APPLICANT: Li, Samuel
; APPLICANT: Wang, Aijun
; APPLICANT: Skeiky, Yasir A.W.
; APPLICANT: Hepler, William
; TITLE OF INVENTION: COMPOSITIONS AND METHODS FOR THE THERAPY AND
; TITLE OF INVENTION: DIAGNOSIS OF PROSTATE CANCER
; FILE REFERENCE: 210121.42717C17
; CURRENT APPLICATION NUMBER: US/09/636,215
; CURRENT FILING DATE: 2000-08-10
; NUMBER OF SEQ ID NOS: 852
; SOFTWARE: FastSEQ for Windows Version 3.0
; SEQ ID NO 435
; LENGTH: 424
; TYPE: DNA
; ORGANISM: Homo sapiens
US-09-636-215-435

Query Match 97.4%; Score 304; DB 4; Length 424;
Best Local Similarity 100.0%; Pred. No. 2.9e-92;
Matches 304; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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Qy          9 GTTTGCTCTGAATTTATTGCGAGTGAAAAACAGAGAAAATCCTCAAGTTTAAGTTTCTGA 68
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        424 GTTTGCTCTGAATTTATTGCGAGTGAAAAACAGAGAAAATCCTCAAGTTTAAGTTTCTGA 365

Qy         69 TAGCAGAGTGTGGGAGTTAGAGCATGGGGAGTCCAGAGGTTCCAGACCCCCAAAGGTCTC 128
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        364 TAGCAGAGTGTGGGAGTTAGAGCATGGGGAGTCCAGAGGTTCCAGACCCCCAAAGGTCTC 305

Qy        129 TACCAGGGCCATCTCCGTTAGTGGCGGTGGCAGCCCCTCTTGTGGCCTTTTTCCTCTCTC 188
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        304 TACCAGGGCCATCTCCGTTAGTGGCGGTGGCAGCCCCTCTTGTGGCCTTTTTCCTCTCTC 245

Qy        189 CAAGGGGTCACCCCGCACCATGCCGCTCCCCCTCATCTATCTTGCCCCCTCCCCACAGGC 248
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        244 CAAGGGGTCACCCCGCACCATGCCGCTCCCCCTCATCTATCTTGCCCCCTCCCCACAGGC 185

Qy        249 CCATCTGCGCTGAACTCTCGCCAGTTCCGAAGTCGGCGAGGGAGGGGGTTTACTTGCCCG 308
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        184 CCATCTGCGCTGAACTCTCGCCAGTTCCGAAGTCGGCGAGGGAGGGGGTTTACTTGCCCG 125

Qy        309 ATCG 312
              ||||
Db        124 ATCG 121
```

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The examiner works a flexible schedule, however she can normally be reached between the hours of 6:30 am to 5:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
07 October 2004